

Commentary

# Health Issues in the Clean Air Act

by Robert Frank\*

*Major conclusions and recommendations of the National Commission on Air Quality on issues of health in the Clean Air Act are presented. The issues revolve mainly about the standard setting processes for ubiquitous pollutants, controlled through ambient air quality standards (Section 109), and for hazardous pollutants controlled through emission standards (Section 112). The conceptual difficulties inherent in the terms "adequate margin of safety" (Section 109) and "ample margin of safety" (Section 112) are discussed. The Clean Air Science Advisory Committee is widely viewed as having a salutary effect on standard setting. The need for maintaining strong research capabilities within the Environmental Protection Agency that are reasonably buffered against sudden disruptive events is emphasized. Mechanisms for achieving this goal through special congressional appropriations are considered.*

## Introduction

Congress, in passing the Clean Air Act of 1970 and the Amendments of 1977, declared that the overriding goal was to protect the public health. Several principles were enunciated, which may be summarized as follows.

- That the Act was to be precautionary and preventive, to assure that harm did not occur.
- That the Administrator of the Environmental Protection Agency (EPA) was to weigh risk, to steer a path short of unachievable standards of proof.
- That in setting ambient air quality standards or emission standards, consideration was to be given to the cumulative effects of a particular pollutant from all its sources, and to the additive and synergistic effects that might arise from exposure to several pollutants. (Synergism, defined as an effect from two or more agents that is greater than additive, has been difficult to demonstrate in inhalation experiments on humans. The evidence to date comes largely from studies on animals and isolated tissue preparations.)
- That the term "public health" was to include the health of susceptible or vulnerable persons. Age, malnutrition, and underlying ill health are among the factors that may contribute to vulnerability.

- That there are inherent uncertainties and gaps in the scientific information bearing on regulatory decisions, due in part to the limited resources available to the agency. Therefore, regulatory decisions must proceed in the face of incomplete knowledge. (Of course, there is intense debate over what constitutes adequate knowledge.)

The National Commission on Air Quality (NCAQ) was mandated by Congress to review the workings of the Clean Air Act. NCAQ's report was submitted to Congress on March 1, 1981 (1). In this brief commentary I would like to describe some of the commission's findings and recommendations related to the standard setting process for several individual standards, and finally, the research conducted or sponsored by EPA to provide a scientific basis for the standards.

## Ambient Air Quality Standards

Air pollutants may be regulated in one of two ways. The pollutants controlled by national ambient air quality standards (NAAQS) qualify by reason of being emitted from a large number and variety of sources and of being widely dispersed. They cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare. Primary NAAQS, as stated in Section 109, are to allow "an adequate margin of safety . . . requisite to protect the public health." The more hazardous air pollutants regulated un-

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der Section 112\* "may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible or incapacitating reversible illness." Accordingly, the latter are to be controlled through emission standards stringent enough to provide "an ample margin of safety."

Such statutory terms have been the storm center of debate because it is pointed out (by some) that safety cannot be demonstrated objectively; instead, it constitutes a judgment of what is an acceptable level of risk (2, 3), and that the language of the Clean Air Act ought to reflect this reality.

It is also argued (by some) that "margin of safety" implies the existence of a threshold concentration below which no adverse effect may occur. But in view of all the factors that may influence susceptibility, only a fraction being recognized or well understood, there cannot be a single threshold for all possible effects for the entire population; and if there were it would be indeterminable. Consequently, those who oppose retaining this phrase would substitute "acceptable risk," "not unreasonable risk," or some similar variant, examples of which may be found in other public health legislation. For example, the Occupational Safety and Health Act (1970) specifies that permanent standards must be economically and technically feasible; the Safe Drinking Water Act (1974; amended 1977): standards shall protect health to the extent feasible; the Toxic Substances Control Act (1976) states that standards shall protect against "unreasonable risk" to health or the environment. Those in support of the original term argue that its ambiguity represents a sort of legal wisdom that provides strong guidance to the administrator while allowing him or her adequate discretion. Moreover, to substitute one of the alternative phrases would be seen symbolically as a retreat from the goals of the Act. As a rationalist, I am inclined toward statutory language that acknowledges the concept of acceptable risk, an approach that governs so many of our personal and social decisions. But as a recent participant in, and observer of, public policy-making, I have come to recognize the importance attached to symbolism. There is general acknowledgment that we now seek estimates of the probability of risk associated with a proposed standard (something akin to quantitative risk assessment) rather than to pursue a fictional or

indeterminable threshold to which a margin of safety can then be added.

A separate yet related issue concerns the weight, if any, to be given to considerations other than health in establishing primary standards: that is, to what extent the multiplicity of costs and benefits associated with a proposed standard, and expressed in economic terms, are to be taken into account. The Act has been interpreted to mean that health alone is to be considered. Economics are to come into play only in the implementation of standards, which strive to be cost-effective. Certainly, the inclusion of cost-benefit analysis in standard setting is compatible with, if not inherent in, the concept of "acceptable risk." The analysis may also be combined with a no-effect or threshold approach, presumably as an aid in determining how much of a margin of safety is to be imposed.

NCAQ recommended retention of the statutory requirement for setting air quality standards "without consideration of economic factors," and also, that EPA as in the past should continue to conduct and publish analyses of the possible economic costs and benefits of the range of standards under consideration. Such analyses, however, were not to be used in determining "whether or at what level the standards should be established."

## Emission Standards

To date, attention has focused principally upon carcinogens among the hazardous substances. Theoretically, there is no concentration of a carcinogen that may not cause cancer. But to promulgate standards that even approach zero emissions for some demonstrated or potential carcinogens could be disruptive to major industries, and hence unacceptable to society.

In seeking to resolve this dilemma, EPA has proposed an Airborne Carcinogen Policy that prescribes in entirety the procedure to be followed in establishing the standard. Evidence is ranked by type: epidemiological information from human populations, lifetime studies on animals, *in vitro* screening procedures such as the Ames assay for mutagenicity, and last, evidence adduced from the physical-chemical properties of the substance. The weight accorded the evidence depends on its level of confirmation. The other factor besides the potency of the carcinogen that contribute to risk are the estimated size of the population that is exposed and level(s) of exposure.

The first attempt to apply the carcinogen policy, in which six candidates were submitted for listing as hazardous pollutants before the Science Advi-

\*Section 112 is entitled National Emission Standards For Hazardous Air Pollutants (NESHAPS).

sory Board Subcommittee on Airborne Carcinogens was largely rebuffed. (The Science Advisory Board, consisting of nonagency scientists, is appointed by the administrator. The six substances reviewed were acrylonitrile, methyl chloroform, methylene chloride, perchloroethylene, trichloroethylene, and toluene.) Clearly there was wide divergence of scientific judgment over what constitutes adequate evidence for listing. The agency is in the process of revising the policy in the light of this experience.

NCAQ recognized the need for more effective action by EPA in dealing with hazardous substances. Since passage of the act over 10 years ago, EPA has listed only seven substances and promulgated standards for four, and these actions were the result primarily of prodding by Congress and public interest organizations. NCAQ recommended that the agency take steps to improve and accelerate the programs for identifying, screening and assessing hazards in moving to a regulatory decision; the results of this effort were to be submitted to Congress. An additional recommendation was made that Congress consider whether to set limits on the time allowed for listing of pollutants.

## Criteria

Certainly, the most time-consuming step in the standard setting process is the preparation of the criteria document by EPA in which all relevant, reliable information on the full range of biological effects of the air pollutant is described. The act does not define public health nor specify "adverse" effects. The question of whether all effects qualify as adverse and are to be protected against has become a pointed issue.

Some medical scientists argue that explicit criteria of adversity are needed (4). For example, in the instance of a functional impediment of the lung, these criteria might specify the magnitude of change required, whether it need be persistent, cumulative, associated with discomfort or disability, and so forth. According to some criteria that have been proposed, symptoms of irritation by themselves, including smarting of the eyes, burning of the throat and cough, would not qualify as adverse. Presumably, any anxiety or sense of distress induced by these symptoms would not qualify either.

The argument for distinguishing between all identifiable effects and those having, or judged to have, consequences for health is based in part on the perception that our technical ability to detect subtle responses to stress is always improving.

We are dealing increasingly with effects that are subliminal, transient, and have no known implications for the well-being of the individual. Hence, so the argument goes, they should be accorded little weight in the setting of standards.

The difficulty in seeking to establish criteria of adversity is that they, owing to our limited knowledge, must inevitably reflect uncertain judgments. The danger is that such criteria will be viewed as dictates that close the door to further research and acquisition of knowledge. Besides, the argument could be made that the definition of an adverse effect is not likely to be resolved scientifically—it is too shrouded in medical and philosophical controversy—and that it rightfully remains a matter of policy.

NCAQ adopted the position that any attempt to limit the scope of health effects by legislation was unwarranted, nor did it recommend that the administrator be required to establish such criteria.

## Clean Air Science Advisory Committee

The watchdog of the standard setting process is the Clean Air Science and Advisory Committee (CASAC), mandated by Congress to review all assembled criteria. In addition, CASAC reviews the staff position paper prepared within EPA, which identifies key findings in the criteria document and provides the scientific argument for the administrator in proposing a new or revised standard. In the judgment of NCAQ, CASAC's contribution has benefited the process enormously. Its reviews, which are conducted before public audiences, have been thoughtful and exacting. CASAC may withhold approval of any criteria document on scientific grounds. While the agency and its team of authors and consultants need not accede to all such criticisms and suggestions, they are under considerable pressure to do so, or at least to provide convincing reason for not complying.

There has been criticism from some quarters of the method of choosing the membership of CASAC. Appointment is made by the administrator after recommendations are received from interested parties. The argument has been made that this role of the administrator is likely to compromise the independence of the committee, and either that selection should be made by a completely independent body such as the National Academy of Sciences or that CASAC should exist apart from EPA. NCAQ's findings did not support this point of view. CASAC has not

only demonstrated ability and independence, but has responded to its huge task in timely fashion, a trait that may lie beyond the ability or inclination of potential caretaker organizations unused to the often pressing needs of a regulatory agency.

CASAC, having recently reviewed its own performance, appears now to be seeking official input into the setting of numerical standards. This step, of course, carries beyond science directly into policy. It may be inherent in the legislation, for Section 109 states that the Committee "shall also advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards."

The issue of what the full scope of CASAC's role in standard setting is to be came to the surface after NCAQ had completed its report. It is one that Congress might choose to clarify. My view is that CASAC, were it to assume this additional responsibility, would stand to sacrifice the appearance, if not the reality, of scientific detachment, which is the essence of its present contribution. At the same time, it would have to establish whatever new credentials were demanded by the expanded role.

The only recommendation made by NCAQ regarding CASAC was that the statutory limitation on its size be removed. Despite the wide diversity of scientific, technical and related subjects confronting CASAC, it is presently held to seven standing members. (The consultants do not vote.)

## Specific Primary Air Quality Standards

As a matter of policy, NCAQ did not attempt to judge the appropriateness or validity of specific numerical air quality standards. However, it did submit brief findings related to these standards.

- The inadequacy of the current total suspended particulates (TSP) standard in protecting public health and welfare was noted. The effect of airborne particulates are now recognized to be intimately related to their size and chemical composition. However, neither of these attributes is reflected in the primary standard, which refers only to mass concentration. Moreover, measurement of TSP mass by the high-volume sampler now in use is imprecise. The collection efficiency of the high-volume sampler changes with wind direction and speed. Were an upper size limit of about 10-15  $\mu\text{m}$  established, the efficiency of the sampler could, through changes in design of the

inlet, be made virtually independent of the wind (5).

Fine particulates (under 2 to 3  $\mu\text{m}$  diameter) are considered more hazardous to health than coarse particulates for both chemical and aerodynamic reasons. (They are more likely to deposit in the periphery of the lung, which favors long retention.) NCAQ recommended that within one year EPA be required to determine whether a fine particulate standard should be established in addition to or as a replacement for the TSP standard.

- NCAQ noted that recent clinical research has forced a re-evaluation of the dose-response relation (in terms of pulmonary function) for sulfur dioxide. Particular reference was made to the study (6) showing that asthmatic subjects exposed by mouth to 0.5, 0.25 and 0.1 ppm of sulfur dioxide during short periods of exercise may undergo bronchoconstriction (airway narrowing). Such findings underscore the importance of research on susceptible members of the population, difficult as this may be to accomplish owing to ethical and legal constraints. NCAQ lacked the time needed to assess the implication of these findings for either the 24-hr standard for sulfur dioxide, or possibly a shorter term standard.

- NCAQ found that the most incisive information on the possible consequences of long-term exposure to ozone may presently derive from research on animals. This research has shown that prolonged exposure to concentrations of ozone at or below 0.2 ppm can cause functional, biochemical, and structural changes involving the small airways and adjacent air spaces analogous to the changes associated with aging and early chronic obstructive lung disease in man (7-9). These studies do require confirmation. But it is important to note that similar adverse effects in the general population can neither be inferred nor ruled out by the results of short-term exposures of human volunteers, while their detection could lie well beyond conventional epidemiological techniques.

NCAQ examined the special problem posed by carbon monoxide at high altitude (10). Carbon monoxide and altitude act in a complementary way to reduce the supply of oxygen to the issues of the body. Consequently, the risk of carbon monoxide to health is likely to be greater at altitude than at sea level, particularly for visitors unacclimated to the reduced ambient oxygen pressure. At what elevation this risk becomes significant is uncertain. Among those who might be most susceptible to the dual stress are persons with cardiovascular, lung or blood disorders (which may be "silent" clinically), pregnant women, and the de-

veloping fetuses. Whether a separate federal high altitude standard for carbon monoxide is warranted remains an open question. About 3% of the nation's population lives at altitudes of 4000 ft or higher, principally in California, Colorado, New Mexico, and Utah. California has adopted an ambient air quality standard for carbon monoxide of 6 ppm (8-hr average) for the region around Lake Tahoe (elevation: 5200 ft). This is 50% more stringent than the national standard.

## EPA Research

Basic, anticipatory and applied research are all vital to the understanding and control of pollutants. As a practical matter, however, the agency's research program must yield to immediate regulatory needs, and applied research with short-term goals becomes most favored. This is unfortunate for basic research nourishes all forms of investigation. With this in mind, the Environmental Research Development and Authorization Act of 1978 was designed to ensure a balanced program. The act stipulated that at least 15% of all research funds at the agency were to be assigned to long-term and anticipatory research. Despite the use of these funds to establish specific programs such as the Research Center Support Program and the Innovative Research Awards Program, the total effort in this direction has been inadequate. (EPA can establish contracts with universities and other institutions through the former program (RCSP); the latter program (IRAP) is designed to support innovative research proposed by the staff at EPA.) NCAQ found instead that environmental emergencies like those at Three Mile Island and Love Canal tend to disrupt programs already underway by forcing major shifts in allocations of personnel and funds. Funds diverted from planned or ongoing programs generally cannot be recovered, and permanent interruption of the work is a consequence. To provide a buffer against this occurrence, NCAQ recommended a congressional appropriation of funds, separate from the agency's regular research budget, to be used solely for research directed toward environmental emergencies. Additional appropriations could be authorized as needed.

Epidemiology among all the research programs at EPA has drawn the greatest criticism. Much of this criticism followed on the heels of the CHES Report, which was released by EPA in 1974 as a compendium of studies done on several communities across the nation (10, 11). Some critics have even questioned EPA's ability, because it is a

regulatory agency, to conduct credible research. EPA has now shifted epidemiological research exclusively to the extramural program.

Within the past few years EPA has responded to much of this criticism. Steps have been taken to ensure the scientific quality and relevance of its research. Formal research committees comprised of both scientific and regulatory personnel now establish long- and short-term priorities. Independent peer review groups examine all proposals for extramural research. NCAQ recommended that the intramural research program be subject to similar examination either by the Science Advisory Board or consultants.

One persistent problem is the difficulty the agency has in attracting and retaining able scientists and research support staff. Its generally superior laboratory facilities—the clinical inhalation laboratory in North Carolina is probably unmatched anywhere—plus the obvious appeal of participating in research that has direct social value are offset by disincentives that spring directly from the agency's regulatory function. These include the vulnerability of intramural research to sudden changes in priorities and funding, heavy administrative burdens, and often lengthy, distracting responses required by the Freedom of Information Act (12, 13). NCAQ recommended that EPA report to Congress on measures that could be used to attract good scientists, but I am skeptical that significant progress will be made in the near future on this matter of fundamental importance.

On balance, NCAQ's findings did not support the suggestion that the research function of the agency be split off and transferred to an organization such as the National Institutes of Health (NIH) in the Department of Health and Human Services. NIH is of course esteemed for its excellent record of research. However, it is not accustomed to the exigencies of regulatory research, including the inevitable abrupt shifts in direction that must be taken, nor to the mechanical, intellectually bland nature of much of the work. NIH might be expected to resist making the necessary adjustments, viewing them as a potential threat to its own distinctive character.

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